

INITIAL STATEMENT OF REASONS
OVERVIEW/NON-CONTROLLING SUMMARY

TITLE 18. PUBLIC REVENUE
REGULATION 1591, MEDICINES AND MEDICAL DEVICES

Regulation 1591 interprets and explains the application of sales and use tax to sales or other transfers of medicines, as defined. It explains when such sales are subject to sales and use tax and when they are not.

Specific Purpose

The purpose of the proposed amendments is to interpret, implement, and make specific Revenue and Taxation Code section 6369. These amendments are necessary to provide guidance to that portion of the public which is affected by this statute.

Factual Basis

The California Sales and Use Tax Law imposes either a sales or use tax on all retail sales of tangible personal property to California consumers, unless otherwise exempted by statute or type of transaction. Generally, doctors are considered consumers of products they use in performance of their medical services. The sale of these products to doctors is taxable unless the item qualifies for exemption, such as the exemption for medicines provided in RTC section 6369.

RTC section 6369, interpreted and implemented by Regulation 1591, provides that sales or other transfers of medicines as defined in the statute are not subject to tax if they are sold or otherwise transferred pursuant to the requirements set forth in the statute. In section 6369, subdivision (b), the Legislature has provided that the term “medicines” means “any substance or preparation *intended* for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and commonly recognized as a substance or preparation intended for that use [emphasis supplied].” Thus, the intent (or professional judgment) of the qualified person (e.g., doctors) ultimately prescribing or furnishing the substance or preparation for treatment is an essential element to the statutory definition of “medicines.” Assuming all the other requirements for exemption are met, the Legislature has set up a statutory scheme where the professional judgment of doctors is deferred to regarding whether they have prescribed or furnished the substance or preparation for use in the treatment of a disease or for some other purpose (i.e., for a purpose that is wholly unrelated to the treatment of a medical condition). The same deference to the professional judgment of doctors and other qualified persons is also required for devices and articles prescribed or furnished under subdivision (c) of RTC section 6369.

The Board has concluded that revisions are needed because Board auditors are erroneously assessing tax on sales of prescription drugs used to treat medical conditions. Specifically, auditors have questioned non-taxed sales of certain substances that have a medical purpose when the eventual application of the specific product sold is for cosmetic purposes. The Board has concluded that to make the determination as to whether or not a product is sold for an exempt purpose when it has a dual use would require auditors to investigate doctors’ practices and to examine patient records, thus violating the doctor-patient privilege.

Subdivision (a)(9)- new subdivision (a)(9)(A) added to clarify that any product approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition is considered a medicine, except for devices excluded from the term “medicine in subdivision (c)(2); current language of subdivision (a)(9) transferred to new subdivision (a)(9)(B) with word “any” capitalized accordingly. Subdivision (b)(1)- phrase “In . . . The” added to clarify that the definition of “medicine” in subdivision (a)(9) is in addition o the definitions of “medicines” contained in subdivision (b).

Pursuant to Government Code section 11346.5(a)(8), the Board of Equalization finds that the adoption of the proposed amendments will not have a significant adverse economic impact on private businesses or persons. The amendments are proposed to interpret, implement, and make specific the authorizing statutes in the context covered by the regulation for greater ease of understanding and to conform the regulation to recent legislation. These changes will clarify the interpretation or administration of the sales and use tax laws. Therefore, the Board has determined that these changes will not have a significant adverse economic impact on private businesses or persons.